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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,514

06/09/2005

Tsuyoshi Naganuma

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EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

08/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/538,514	<b>Applicant(s)</b> NAGANUMA ET AL.	
	<b>Examiner</b> WALTER E. WEBB	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,8,9,11,12 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,9,11,12 and 27-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/2010</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/8/2010 has been entered.

Applicants' arguments, filed 4/8/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112--New***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 9, 11, 12 and 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 29 and 30 contain the trademark/trade names STARCH 1500 and PCS. Where a trademark or trade name is used in a claim as a limitation to identify or

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describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe pregelatinized corn starches and, accordingly, the identification/description is indefinite.

### ***Claim Rejections - 35 USC § 103***

Claims 1, 8, 9, 11, 12 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitazawa et al., (US 5,387,603) in view of Ishihara et al., (US 2002/0177593) and in further view of Salpekar et al., (US 4,757,090) and Shah (US 5,370,878) and Tasaka et al., (US 2002/0173526).

Kitazawa et al. teaches the compound of claim 1 (KMD-3213) (see col. 62, claim 10), and a method of using the compound for the treatment of dysuria (see col. 1, lines 57-59.). The compound or the pharmaceutically acceptable salts thereof can be administered orally as tablets and capsules in accordance with conventional molding methods (see col. 16, lines 15-23). In regard to **claim 28**, the reference teaches an acceptable dosage range from about 0.5 to 500 mg per adult human by an oral administration per day (see col. 16, lines 23-25).

Kitazawa et al. does not teach combining the compound with D-mannitol, two types of pregeletinized starch, sodium lauryl sulfate, or a lubricant such as magnesium stearate.

Ishihara et al. teaches a method for treating dysuria with agents such as KMD-3213 (see paragraphs [0559], [0553], [0556], and [0577]). The agents can be administered in capsule or tablet form further comprising pregelatinized starch, a light-shielding coating agent like titanium oxide (claims 11, 12), D-mannitol, lubricants such as magnesium stearate, and sodium lauryl sulfate (see paragraphs [0618], [0626], [0620], and [0596]). The pharmaceutical compositions are taught to be produced according to a conventional method in the field, for example, a method described in The Japanese Pharmacopoeia (see paragraph [0619]).

The combination of Kitazawa et al., and Ishihara et al., differs from the instant claims insofar as it does not teach Starch 1500 and PCS.

Shah teaches use of either partially or completely pregelatinized starch as disintegrants, such as Starch 1500, for a short dissolution time (see col. 3, lines 56-64). Shah also teaches combining disintegrants (see Table 1).

Tasaka et al. teaches the use of partially pregelatinized starch PCS for quick release preparations (see pg. 15, paragraph [0289]). PCS is taught to disintegrate a granule by adsorbing water, causing swelling (see Id). Disintegrating agents can be used alone or in combination of two or more (see Id).

Salpekar et al. teaches that the use of pregelatinized starch directly attributes to a short dissolution time, e.g. about 20 minutes or less for 80% or more of the active

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compound (see abstract, and col. 2, lines 60-66). The reference further teaches adding compatible mixtures of two or more lubricants such as sodium lauryl sulfate, magnesium stearate at 0.10 to about 1 percent based on the dry weight of the composition (**claim 31**) (see col. 3, lines 13-23). These amounts are such that disintegration, dissolution time will not be increased (see col. 3, lines 5-10). Salpekar does not teach a compound formula of claim 1.

Generally, it is also *prima facie* obvious to select a known material based on its suitability for its intended use (see MPEP 2144.06). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function (see *Id.*). Thus it would have been obvious to use D-mannitol, pregelatinized starch, magnesium stearate, sodium lauryl sulfate, light-shielding to formulate the capsule composition of Kitazawa et al., as taught by Ishihara et al, Salpekar et al., and Shah.

The artisan would have been further motivated to use partially pregelatinized starch, starches such as Starch 1500 and PCS, for their recognized ability to impart a short dissolution time, as taught by Shah and Tasaka. Since pregelatinized starches have been recognized for imparting a short dissolution time of about 20 minutes or less for 80% or more of the active compound to dissolve, the artisan would reasonably expect Starch 1500 and PCS to impart a similar dissolution time.

Generally, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See MPEP 2144.05. Since the claimed concentration for the lubricant and indole compound

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overlaps with concentrations taught in Salpekar et al. and Kitazawa et al. a prima facie case of obviousness exists.

### ***Response to Arguments***

A declaration under 37 C.F.R 1.132, filed 4/8/2010 by Tsuyoshi Naganuma, was submitted with data comparing different formulation for several capsules.

The Examiner agrees that the showing supports an unexpected result. It appears that the specific combination of PCS and Starch 1500 are essential for providing the claimed dissolution rate. However, the recitation of the terms “PCS” and “Starch 1500” causes the claims to be indefinite since these terms are trademarked, and trademarks cannot be used to identify any particular material or product. Accordingly, the claims are not commensurate in scope with the showing. The Examiner recommends amending the claim to recite the distinguishing and identifying characteristics “PCS” and “Starch 1500”, which are attributable to the showing.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612